EXHIBIT A

AO 88A (Rev. 02/14) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Massachusetts

In Re: New England Compounding Pharmacy, Inc. Products Liability Litigation

Plaintiff

v.

Tennessee Clinic Defendants

Defendant

Civil Action No. MDL No. 1:13-md-02419

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: New England Compounding Pharmacy, Inc. d/b/a New England Compounding Center ("NECC")

(Name of person to whom this subpoena is directed)

☑ *Testimony:* **YOU ARE COMMANDED** to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about the following matters, or those set forth in an attachment:

Place:	Date and Time:
Nutter, McClennen & Fish LLP 155 Seaport Blvd. Boston, MA 02210	May 13-14, 2015 9:00 a.m. EDT

The deposition will be recorded by this method: Stenographical means and video

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

See attached Notice of 30(b)(6) Deposition and duces tecum

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 4/17/15

CLERK OF COURT

OR

Signature of Clerk or Deputy Clerk

Attorney's signature

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Tennessee Clinic Defendants, who issues or requests this subpoena, are:

Chris J. Tardio; 315 Deaderick Street, Suite 1100, Nashville, TN 37219; chris@gideoncooper.com; (615) 254-0400

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. MDL No. 1:13-md-02419

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* _____

on *(date)* _____ .

❒ I served the subpoena by delivering a copy to the named individual as follows: _____

_____

_____ on *(date)* _____ ; or

❒ I returned the subpoena unexecuted because: _____

_____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of $ _____ .

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:

(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or

(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person

(i) is a party or a party's officer; or

(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:

(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and

(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***

(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.

(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:

(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.

(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;

(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);

(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or

(iv) subjects a person to undue burden.

(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:

(i) disclosing a trade secret or other confidential research, development, or commercial information; or

(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.

(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:

(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and

(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:

(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.

(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.

(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.

(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***

(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:

(i) expressly make the claim; and

(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.

(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.

The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	MDL No. 2419 Dkt. No 1:13-md-2419 (RWZ)
THIS DOCUMENT RELATES TO: All Cases	

Notice of 30(b)(6) Deposition

Defendants Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John Culclasure, MD; Debra Schamberg, RN, CNOR; Vaughan Allen, MD; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; Kenneth Lister, MD, PC; and Donald E. Jones, MD (collectively "Tennessee Clinic Defendants"), pursuant to Federal Rule of Civil Procedure 30(b)(6), come now and give notice that the oral and videotaped deposition of New England Compounding Center (hereinafter "NECC"), as an organization, will be taken on the topics detailed below. NECC shall identify the person(s) who will speak on its behalf on each topic at least seven (7) days before the deposition(s).

The deposition will be taken on May 13-14, 2015, beginning at 9:00 a.m. (EDT) on May 13, and continuing until completed. The deposition will take place at the offices of Nutter, McClennen & Fish LLP, 155 Seaport Blvd., Boston, MA 02210. The deposition will be recorded by stenographical means and by video.

Pursuant to Federal Rule of Civil Procedure 30(b)(6), NECC's designee(s) shall be prepared to testify regarding the following subjects[1]:

Basic corporate structure and background

1. NECC's basic corporate structure from 2006 to the time of the bankruptcy, including ownership and governing persons, and NECC's relationship to each of the "Affiliated Entities."[2]
2. NECC's licensure and any certifications it held from 2006 to the time of the bankruptcy.
3. NECC's business relationship with ARL from 2006 to the time of the bankruptcy.
4. Identification of NECC's employees from 2006 to the time of the bankruptcy, and their duties.
5. Whether NECC (1) had a duty to the Plaintiffs to comply with the recognized standard of acceptable professional practice for compounding or manufacturing

[1] Unless otherwise specifically stated, the timeframe for the topics is 2006 through the time that NECC ceased operations.

[2] These include:

1. Ameridose
2. Medical Sales Management
3. Medical Sales Management, SW
4. 203 Flanders Road, LLC
5. 205 Flanders Road, LLC
6. Alanus Pharmaceuticals
7. AMD
8. Cadden Family – 2012, LLC
9. Cardo Properties, LLC
10. Conigliaro Block, Inc.
11. Conigliaro Family Investments, LLC
12. Conigliaro Industries, Inc.
13. GDC Holdings, Inc.
14. GDC Properties Management, LLC
15. Hunter Holdings, LLC
16. L&S Creations, Inc.
17. MSM, Inc.
18. MSM SW, Inc.
19. Nationwide Foam, Inc.
20. Nationwide Recycling Sales Management, Inc.
21. Physicians Choice Medical Marketing, LLC
22. Stone House Realty Group, LLC.

MPA and to use reasonable care when compounding the MPA at issue and (2) breached that duty, (3) causing injury to Plaintiffs.

6. NECC's compliance with state and federal regulations applicable to drug manufacturers, compounding pharmacies, and/or traditional pharmacies, from 2006 to the time of the bankruptcy.
7. Whether NECC had sufficient and adequate facilities and adequately trained staff to produce sterile, safe MPA from 2006-12.
8. NECC's compounding practices, standard operating procedures, pharmacist training, and risk management protocols.[3]
9. NECC's interactions and communications with UniFirst regarding UniFirst's cleaning of the cleanroom where the MPA at issue was compounded.

Interactions with federal and state agencies

10. Investigations and actions by the FDA, Massachusetts Board of Pharmacy, or other federal or state regulatory agencies, specifically:

    a. FDA investigation in March 2002 and subsequent inspection on April 16, 2002 (and related Form 483)

    b. FDA investigation in October 2002 and subsequent inspection (Form 483 issued February 10, 2003)

    c. 2004 inspections of NECC by the FDA and Massachusetts Board of Pharmacy

    d. 2004 private censures by the Massachusetts Board of Pharmacy

    e. FDA investigation and inspection conducted in September 2004 related to NECC production of trypan blue

    f. The 2006 Warning Letter issued to NECC (including the findings underlying the letter as described in the letter)

[3] *See* Second Amended Master Complaint, ¶234(l).

g. 2006 audits of NECC by Pharmacy Support, Inc.

h. June 2007 MedWatch reports to FDA about NECC related to re-packaging of Avastin

i. June 2008 complaints to the FDA related to NECC betamethasone

j. October 31, 2008, letter to NECC asserting that FDA has the authority to take action and that FDA will re-inspect NECC

k. Reports from anonymous informants in October 2009 and July 2010 about Ameridose and its leadership (leadership shared with NECC) forging sterility documents and knowingly not following proper sterility procedures

l. 2011 reports from the Colorado Board of Pharmacy regarding NECC's operation

m. May 24, 2011, inspection by Massachusetts Board of Pharmacy.

11. Any other communications or interactions between state or federal regulatory agencies and NECC not specifically referenced in 10(a)-(m).

12. The inspection of NECC by the FDA following the meningitis outbreak and its results.

NECC's interactions[4] with customers

13. The accuracy of NECC's customer lists as published by the CDC after the outbreak.[5]

14. NECC's marketing of its capabilities and services to Tennessee health care providers from 2006 to the time it ceased operations.

15. NECC's representations to its customers and prospective customers from 2006 to the time of the outbreak regarding its compliance with USP 797, its compliance

[4] Herein, when "NECC" is used to describe a topic related to NECC's communications or interactions with customers, "NECC" is intended to include its employees and agents, including employees and agents of its affiliated companies (specifically its marketing arm, Medical Sales Management).
[5] *See, e.g.*, http://www.fda.gov/downloads/Drugs/DrugSafety/FungalMeningitis/UCM325466.pdf.

with industry standards for sterility, and its compliance with industry standards for aseptic compounding.

16. Whether any health care provider customer or prospective customer of NECC, from 2006 to the time NECC ceased operations, performed a site visit of NECC and, if so, identification of the health care provider, date of the inspection, whether it was announced or unannounced, results of the inspection, and whether the customer thereafter purchased medication from NECC.

17. The due diligence generally conducted by health care provider customers of NECC before purchasing medication from NECC.

18. Whether NECC sold MPA to its customers with the expectation it would be resold or whether it sold MPA to customers with the expectation it would be used in the provision of health care services.

19. Representations and recommendations NECC made to its health care provider customers (specifically its Tennessee customers) from 2006 to the time it ceased operations regarding:

    a. Whether it made and sold its medications in compliance with all applicable pharmaceutical laws

    b. Its regulatory history, including recalls, licensure actions, and investigations[6]

    c. Its history of product liability suits[7]

[6] *See* Second Amended Master Complaint, ¶234(m), (n).
[7] *See* Second Amended Master Complaint, ¶234(o).

d. Its ordering process (specifically whether it required patient-specific prescriptions when filling orders for medications and whether this was necessary to comply with state or federal law)

e. Beyond-use dates for and recommended storage of MPA[8]

f. Whether NECC was a reputable supplier of medications.[9]

20. Whether NECC expected its customers to rely on the representations it made to them regarding its compounding processes, sterility processes, and compliance with state and federal requirements.

21. Whether NECC expected its customers to rely on the representations it made regarding the legality of its ordering process.

22. Whether NECC, directly or through its marketing employees and agents, honestly and truthfully marketed and sold its products to customers, including the Tennessee Clinic Defendants.

23. The on-site audit of NECC by Brigham & Women's Hospital in May 2012.

24. NECC's relationship with Medical Sales Management[10] and Medical Sales Management's marketing and sale of NECC drugs to customers.

Interactions with Tennessee Clinic Defendants

25. Any and all of NECC's interactions, either directly or through its employees, agents, or affiliated companies, with the Tennessee Clinic Defendants.

[8] *See* Second Amended Master Complaint, ¶234(r).
[9] *See* Second Amended Master Complaint, ¶234(u).
[10] Or Medical Sales Management, SW.

Production of MPA and batches at issue

26. NECC's process for compounding preservative-free MPA from 2010 through the time it ceased operations, including employees involved, their training, and their duties; processes to ensure sterility (including autoclaving of the batches and whether autoclaving was done for the USP-required 20 minutes); procedures to obtain outside testing; procedures to ensure compliance with USP 797 or other industry standards; ingredients used; and recipes used.
27. NECC's process for outside testing of batches of medications (including, specifically, NECC's use of ARL to test the contaminated batches and whether that testing complied with USP standards, specifically USP 71).
28. NECC's process for producing, labeling, and shipping the contaminated batches of MPA.
29. NECC's process for keeping records of production, sterilization, and testing of batches of medications.
30. Whether NECC utilized fictitious labeling, including fictitious expiration dates, on its medications sold to health care providers to conceal the use of expired ingredients.
31. Whether any customer of NECC utilized individual patient-specific prescriptions when ordering medications from NECC.

Documents

32. The documents the witness(es) is requested to produce in the *duces tecum* attached as an exhibit to this Notice.

DUCES TECUM

[DOCUMENTS TO PRODUCE]

Instructions:

1. *Produce the documents organized by number or description such that that the documents can be linked to a numbered request.*

2. *To the extent these documents can be provided electronically by posting to a web-based repository or provided on CD or flash drive, that is preferable.*

3. *Should these documents already be housed on a repository for this litigation or some other web-based repository, identification of the Bate-stamp number(s) or range(s) of the responsive documents is sufficient, so long as the Bate-stamp numbers are provided in response to each numbered request to ensure the Defendants can identify which documents are responsive to which request. (Simple reference to a repository or 40,000 documents for each request is not a sufficient response to enable these Defendants to identify specific responsive documents.)*

Documents:

1. The personnel files for:

    a. Barry Cadden
    b. Glenn Chin
    c. Gene Svirskiy
    d. Christopher Leary
    e. Joseph Evanosky
    f. Scott Connolly
    g. Joseph Connolly
    h. Sharon Carter
    i. Alla Stepanets
    j. Greg Conigliaro
    k. Robert Ronzio
    l. Kathy Chin
    m. Michelle Thomas
    n. Carla Conigliaro
    o. Doug Conigliaro
    p. Any other person involved in the manufacture or compounding of batches 05212014@68; 06292012@26; 08102012@51.

2. Documents related to internal or external sterility testing of batches 05212012@68; 06292012@26; 08102012@51.

3. Any corporate minutes, memoranda, or meeting summaries from corporate meetings from 2006 through the outbreak related to:

    a. Problems with NECC's sterility processes

    b. The use of patient-specific prescriptions or patient name lists in the ordering process

    c. The Tennessee Clinic Defendants.

4. Any customer file maintained for any of the Tennessee Clinic Defendants.

5. Any internal communications or memoranda mentioning the Tennessee Clinic Defendants from prior to September 20, 2012.

6. Any letters, emails, faxes, or documentation of phone conversations with the Tennessee Clinic Defendants.

7. Any documents related to site visits or inspections conducted by customers of NECC from 2006 to the time of the outbreak.

8. Any internal documents reflecting NECC's failure to comply with USP 797 in the compounding of sterile medications prior to September 18, 2012.

9. Any internal documents, memoranda, or emails reflecting training or instruction to NECC sales people or discussions among NECC employees related to whether a customer was required to send a patient-specific prescription or a list of patient names.

10. Copies of the emails referenced in Paragraphs 92-101 of the NECC Criminal Complaint.

11. Copies of the emails and external communication referenced in Paragraphs 104-08 of the NECC Criminal Complaint.

12. Any communications from customers or potential customers of NECC from 2006 to the time of the outbreak inquiring as to:

    a. Whether it made and sold its medications in compliance with all applicable pharmaceutical laws

    b. Its regulatory history, including recalls, licensure actions, and investigations[11]

    c. Its history of product liability suits[12]

[11] *See* Second Amended Master Complaint, ¶234(m), (n).

d. Its ordering process (specifically whether it required patient-specific prescriptions when filling orders for medications and whether this was necessary to comply with state or federal law)

e. Beyond-use dates and recommended storage of MPA[13]

f. Whether NECC, prior to September 2011, was a reputable supplier of medications.[14]

13. Documents in NECC's possession reflecting the due diligence conducted by the following health care institutions before purchasing from NECC:

a. University of Pittsburgh Medical Center - Pittsburgh, PA
b. New York Presbyterian – Weill Cornell - New York, NY
c. Mayo Clinic Health System in Fairmont - Fairmont, MN
d. Massachusetts General Hospital - Boston, MA
e. Brigham and Women's Hospital - Boston, MA
f. Northwestern Memorial Hospital - Chicago, IL
g. University of California, San Francisco Medical Center - San Francisco, CA
h. Vanderbilt Medical Group Clinic Pharmacy - Nashville, TN
i. Erlanger Health System - Chattanooga, TN
j. Centennial Medical Center - Nashville, TN
k. Gateway Medical Center - Clarksville, TN
l. Summit Surgery Center - Hermitage, TN.

14. Order forms for orders of MPA in 2011-12 by the following NECC customers:

a. University of Pittsburgh Medical Center - Pittsburgh, PA
b. New York Presbyterian – Weill Cornell - New York, NY
c. Mayo Clinic Health System in Fairmont - Fairmont, MN
d. Massachusetts General Hospital - Boston, MA
e. Brigham and Women's Hospital - Boston, MA
f. Northwestern Memorial Hospital - Chicago, IL
g. University of California, San Francisco Medical Center - San Francisco, CA
h. Vanderbilt Medical Group Clinic Pharmacy - Nashville, TN
i. Erlanger Health System - Chattanooga, TN
j. Centennial Medical Center - Nashville, TN
k. Gateway Medical Center - Clarksville, TN
l. Summit Surgery Center - Hermitage, TN.

15. Copies of the Quarterly Assurance Report Cards for all quarters in 2009-12.

16. The cleaning logs for Cleanroom 1 from 2010-12.

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[12] *See* Second Amended Master Complaint, ¶234(o).
[13] *See* Second Amended Master Complaint, ¶234(r).
[14] *See* Second Amended Master Complaint, ¶234(u).

17. Surface and air testing or sampling results (including gloved fingertip sampling results) from 2010-12.

18. Autoclaving records for batches 05212014@68; 06292012@26; 08102012@51.

19. A copy of NECC's standard operating procedures or other internal policies or procedures related to the following:

    a. The ordering process
    b. Marketing of its medications to health care provider customers
    c. Production of sterile medications
    d. Maintaining the sterility of the NECC environment.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

/s/ Chris J. Tardio
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Attorneys for the Tennessee Clinic Defendants

* Admitted pursuant to MDL Order No. 1.
** Admitted pro hac vice.

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 17th day of April, 2015. Additionally, the subpoena and notice are being served on the following by email.

Daniel M. Rabinovitz
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One Beacon Street
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Counsel for Gregory Conigliaro, NECC's Registered Agent

Paul Moore
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Counsel for NECC

/s/ Chris J. Tardio
Chris J. Tardio